

Summary of the On-Site Assessment Committee Meeting June 30, 1998

The On-Site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Monday, June 30, 1998, at 8:30 a.m. Central Daylight Time (CDT) as part of the Fourth NELAC Annual Meeting in San Antonio, TX. The meeting was led by its chair, Mr. Wayne Davis of the South Carolina Department of Health and Environmental Control. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

Following a description of the facilitator's role in ensuring the committee's agenda, Mr. Davis called the meeting to order with an overview of the agenda and an introduction of committee members. He introduced several transitional members - outgoing members Mr. Gary Bennett, Mr. Steven Ankabrandt and Mr. Roy Covert, and incoming members Mr. Charles Dyer, Ms. Kelly Wilson and Mr. Jack Hall. Mr. Davis also stated the committee's charge.

CHANGES TO CHAPTER 3 STANDARDS

The committee explained an error in printed copies of the proposed changes to the standard. The proposed changes as printed for the meeting do not reflect a renumbering of Section 3.2. The existing Section 3.2.2 (Basic Qualifications) has been renumbered 3.2.1. Section 3.2.4 (Assessor Qualifications) has been renumbered 3.2.2. The Section 3.2.3 title (Additional Qualifications) has been eliminated and the section's text has been added to Assessor Qualifications. Section 3.2.1 (Training) has been renumbered 3.2.3.

Section 3.2 - On-Site Assessment Personnel - Proposed changes to this section generated considerable discussion.

- 3.2.1 - Basic Qualifications - The committee explained that they have received word that NELAP will not have the resources to provide oversight for assessor training programs. Consequently, the committee is investigating alternatives. It was suggested that a proposed parenthetical language addition concerning this investigation be withdrawn. Agreeing that undecided items not be included in the standard, the committee withdrew the proposed addition. An attendee noted that many states might not be able to afford to send their assessors to the proposed refresher training annually. The committee responded that they hoped a significant amount of travel would not be required, especially if someone like the Registrar Accreditation Board (RAB) handled training oversight and multiple training providers were available. The committee also pointed out that the proposed refresher training was a one-day course unlike the five-day initial training course. Another attendee questioned the practicality of travel for Pacific rim territories for only a one-day course. There was considerable discussion of the requirement that assessors meet training requirements within 5 years of the date that the first Accrediting Authority is granted NELAP recognition. Some attendees felt that 5 years is too long. In response to this discussion, the committee suggested that basic course requirements be met within 1 year

of the date that the first Accrediting Authority is granted NELAP recognition and technical course requirements be met within 3 years. A second suggestion was made that basic course requirements be met within 2 years of the date that the first Accrediting Authority is granted NELAP recognition and technical course requirements be met within 4 years. An informal poll of the attendees favored the 1-year/3-year option over the 2-year/4-year option. However, several attendees representing states that have already applied for NELAP recognition under the 5-year rule indicated that they have limited resources and may not be able to budget for training within 1 year. These attendees considered the 1 year to be too short and strenuously objected to “changing the rules in the middle of the game.” The committee noted that although it is unfortunate that the standards are being developed simultaneously rather than sequentially, the standards continue to be a work in progress. As a compromise, the committee settled on the 2-year/4-year option.

- 3.2.3 - Training - The proposed basic assessor and technical training courses generated considerable discussion. Some attendees considered the additional technical training courses unnecessary. The committee explained that the intent of the technical training requirement is to ensure the technical competence of each assessor and to assure the reciprocity of each audit. The committee also explained that the technical courses are not meant to reproduce an academic curriculum in each of the subject courses, but to train the assessors in how to review data and audit each subject. After hearing the committee’s intent, an attendee suggested changing the title of the technical training course. The committee took the suggestion under advisement.

Section 3.3 - Frequency of On-Site Assessments - Section 3.3 generated limited discussion. Mr. Davis announced that the proposed change in 3.3.2 (Follow-up Assessments) to 30 working days was being withdrawn. The board has requested that all references in the standard be to calendar days for consistency’s sake.

Section 3.4 - Pre-Assessment Procedures - The only changes to this section, the deletion of a proposed reference to NELAP approval of checklists in 3.4.4 (Assessment Documents), a change in 3.4.5 (Confidential Business Information (CBI) Considerations) to 21 calendar days as the period allowed a laboratory to support CBI claims, and the addition of 3.4.6 (National Security Considerations) in response to a Department of Defense request, generated little discussion.

Section 3.5 - Assessment Schedule/Format - Discussion of proposed changes to this section centered around the effect an enforcement action or its associated investigation would have on the proposed deadline for the issuance of a deficiency report or resulting corrective action report. The committee stressed that they had no authority in potential criminal investigations. After considerable discussion, the last sentence of the section was changed to read, “An exception to these deadlines may be necessary in those circumstances where a possible enforcement investigation or other action has been initiated.” Additionally references to “30 working days” were changed to “45 calendar days” for consistency.

Section 3.6 - Standards for Assessment - Proposed changes to this section generated moderate discussion.

- 3.6.1 - Assessor Training Manual - The committee explained that they had received direction at the last meeting to detach the Assessor Training Manual from the standard. This standalone guidance document has been rewritten since the last interim meeting. There was some discussion of the new NELAC Web Page and whether or not its address would change in the future. In response to an attendee's request, the committee declined to state explicitly the Web address for the NELAC Home Page in 3.6.1 since the address has changed so often in the past.
- 3.6.3 - Checklists - The committee pointed out a proposed addition to the first sentence of this section. The phrase "as documented in the NELAP Assessor Training Manual" has been added since the manual has been detached from the standard. In light of previous discussion of the inadvisability of including references to items which are not yet final in a standard, the proposed note that checklists are being developed was stricken.
- 3.6.4 - Assessment Standards - The proposed addition of "but are not limited to" in the opening sentence was withdrawn.

Section 3.7 - Documentation of On-Site Assessment - There was considerable discussion of whether assessor checklists would be part of the standard, part of the Assessor Training Manual, or a separate document. An attendee commented that the checklists are an intermediary tool rather than a primary standard. Since the standard will include by reference other documentation, the committee was cautioned against being too specific in their language.

- 3.7.2 - Report Format - In light of discussion of whether the checklists would be included in the standard, it was suggested that the proposed language addition "and/or checklist" be withdrawn. The committee agreed to withdraw the proposed addition. The sentence now reads, "The Findings and Requirements Section must be referenced to the NELAC standards so that both the finding (deficiency) is understood and the specific requirement is outlined." There was some discussion of consistency of language between "assessment" report and "deficiency" report. The committee tabled this language issue for future consideration. In subsequent conversation with Ms. Margaret Prevost, chair of the Accreditation Process Standing Committee, it was mutually agreed to use the term "assessment report" in both standards.
- 3.7.4 - Release of Report - It was suggested that language similar to that added in 3.4.6 concerning national security considerations be added to this section. The committee considered adding the last sentence of the proposed 3.4.6 language addition verbatim to 3.7.4. There was considerable discussion, however, of whether the last sentence of 3.4.6 addresses the issue of release of report in 3.7.4. The committee also noted that information controlled for national security reasons would not be included in the report in the first place, so it would not be an issue for release of the report. After some word-smithing discussion, the committee decided to add the phrase "and information related to national security" after "all Confidential Business Information" in the third sentence of 3.7.4.

- 3.7.6 - Record Retention Time - In the interest of consistency, it was decided to return to the standard's original language stipulating retention for 10 years.

TRAINING COURSES AS PROPOSED IN CHAPTER 3

Considerable discussion pertaining to assessor training had already taken place in discussion of the time frame outlined in Section 3.2.1 (Basic Qualifications) for basic and technical training. In more general discussion of training courses, the question was raised of who would provide funding for training. The committee responded that it was their understanding that NELAC would be removed from the funding issue and that funding would be decided by the relationship between whomever provided oversight and the training providers. The laboratories will fund their own certifications through their relationships with the training providers. There was some discussion of whether there is an economic drive for laboratories to obtain NELAC accreditation. An attendee commented that the technical training courses as outlined in the standard needed to be fleshed out. The committee noted that it is their intent to focus on the technical training courses in the coming year. Additionally, it was noted that the training courses need to include regulatory issues. A committee member pointed out that the training courses pertain to the assessment of technical competence to perform specific analyses and not to a regulatory compliance audit. Since regulatory issues are addressed in the audit, however, the committee tabled regulatory training issues for future consideration.

ASSESSOR TRAINING MANUAL AS PROPOSED IN STANDARDS

Mr. Davis stressed that the Assessor Training Manual is a draft. The committee has made its best effort based on directives received from the membership at the last interim meeting. It was agreed that the title of the manual be changed to NELAP Laboratory On-Site Assessment Training Manual. The committee pointed out that this would be an editorial change and that all references to the manual in the standard would also have to be changed. The committee also stated that “auditor” would be globally changed throughout the document to “assessor.” In ensuing discussions of the first three chapters of the manual, the committee repeatedly reminded attendees that the manual is intended for guidance only. Time constraints permitted the detailed discussion of only Chapters 1, 2, and 3. The chair requested the submission of any additional comments on the training manual in written form by September 30, 1998.

- Chapter 1 - Introduction - An attendee pointed out a typographical error in the footnote at the bottom of the first page. The first sentence of the footnote should read, “This version of the manual reflects the draft NELAC standards as of July 31, 1997.” It was also noted that for consistency the description of Chapter 3 given in Section 1.2 should reference “conformance” rather than “compliance.”
- Chapter 2 - NELAC Overview - In order to be consistent with language in NELAC Standard Chapter 4, the word “grant” was substituted for the word “award” in the last sentence of the second paragraph of Section 2.3. It was proposed that “responsible party of record” be replaced with “technical director” based on proposed language changes to NELAC Standard Chapter 4. The committee decided that it would make that change only after the proposed language change was passed by conference vote.

- Chapter 3 - Organization and Management - An attendee commented that Section 3.1.6 does not define a Quality Assurance Officer's "appropriate training and experience." The committee referred to NELAC Standard Chapter 5, and declared this an issue for the Quality Systems Committee. The committee also pointed out that this is a guidance document and is not meant to provide standard definitions. Based on the previous day's discussion of managerial review in the Quality Systems Committee meeting, it was agreed that the note in the fourth bulleted item in Section 3.1.6 deeming internal audit documents "off limits" be deleted. Minor language changes were proposed and accepted for clarification throughout the chapter. The committee was generally amenable to minor language changes which did not conflict with the standard. There was considerable discussion of what is meant by "latest PT results" in the second sentence of Section 3.1.7. The committee reemphasized that the manual is a guidance document and that PT results should be obtained as appropriate to the accreditation status of the laboratory. The committee took suggestions that the language be modified under advisement. As in previous meetings, there was considerable discussion of health and safety issues pertaining to NELAC assessment. The committee pointed out that the intent of the assessment is not to perform an OSHA inspection. An assessor can only document that the laboratory has in place required documentation and that they are following their own health and safety procedures. Several attendees strenuously objected to any inclusion of health and safety references in the manual's language. The committee agreed to strike "referenced Health and Safety Procedures" from the second paragraph of Section 3.2. For clarification several references to "NELAC" were changed to "NELAP." It was noted that nowhere in the NELAC standards, apart from two exceptions concerning specific methods or EPA guidelines, is there a provision to cite a laboratory for the use of an expired and unverified standard. It was generally agreed that this issue should be addressed with NELAC Standard Chapter 5 (Quality Systems).

NELAC PARAMETER CHECKLISTS

Mr. Davis referred attendees to the strategy paper for the committee's development of NELAC parameter checklists included in the conference packet. The strategy paper addresses the issue of method-based checklists versus performance-based checklists. The committee has taken a method-specific approach based on current EPA programs. The committee explained that they had arrived at the strategy based on guidance provided by the Policy and Structure standard's tiered system of accreditation. This tiered system does go down to the method and analyte level. The committee acknowledged that the checklists are still early in their developmental process, and welcomed comments. Mr. Davis explained that this is a transitional time. EPA has begun movement toward a performance-based measurement system (PBMS), but there still exist some programs that specify certification by method.

Representative checklists have been posted on the NELAC Home Page. Since not all attendees have access to the Worldwide Web, an overhead of the "Volatile Organic Compounds - GC/MS" checklist was briefly projected in order to receive comments on format. A participant from the regulatory sector commented that he is more interested in the content at this time because content drives format. A lengthy discussion of method-based versus performance-based checklists ensued. At least one participant noted that standardized methods have specific requirements, and

if the laboratory is not fulfilling those specific requirements then the laboratory is not following the standardized method and should not be certified. Additional discussion compared a regulatory atmosphere to a public health atmosphere. Participants from the laboratory community asserted that laboratories would not be willing to perform analyses that are not cost-effective. Committee members pointed out that in cases of litigation the emphasis would be on specific facts. A participant from ELAB noted that the intent of developing assessor training courses and parameter checklists is to standardize the assessment process and, consequently, produce these facts.

CONCLUSION

Mr. Davis expressed his appreciation for the opportunity to work out the details of the on-site assessment process, and especially the on-site assessment checklists, in a consensus-building forum. The meeting was adjourned at 5:00 p.m. CDT.

ACTION ITEMS
On-Site Assessment Committee Meeting
June 30, 1998

Item No.	Action Item	Date To Be Completed
1.	Committee to receive comments on the On-Site Assessment Training Manual from conference membership.	September 30, 1998
2.	Committee to decide title change for NELAC Technical Training Courses for Assessors.	August 15, 1998
3.	Committee to examine consistency of standard's language between "assessment report" and "deficiency report."	Complete
4.	Committee to decide the need for inclusion of regulatory training issues in assessor training courses.	December 1, 1998
5.	Committee to make global editorial change of Assessment Training Manual title in the standard.	December 1, 1998
6.	Committee to make global editorial change of "auditor" to "assessor."	December 1, 1998
7.	Committee to propose change of "responsible party of record" in Assessment Training Manual Section 2.3 to "technical director" if the related proposed language change to NELAC Standard Chapter 4 is passed by conference vote.	August 15, 1998
8.	Committee to examine language referencing "latest PT results" in Assessment Training Manual Section 3.1.7, and to change if deemed appropriate.	December 1, 1998

PARTICIPANTS
On-Site Assessment Committee Meeting
June 30, 1998

Name	Affiliation	Phone Numbers
Mr. R. Wayne Davis, Chair	South Carolina Department of Health and Environmental Control	T: 803-935-6856 F: 803-935-6859 E: davisrw@columbia36.dhec.state.sc.us
Mr. Steven D. Baker	Arizona Department of Health	T: 602-255-3454 F: 602-255-3462 E: sbaker@hs.state.az.us
Mr. Gary K. Bennett	USEPA/Region 4	T: 706-355-8551 F: 706-355-8508 E: bennett.gary@epamail.epa.gov
Ms. Rosanna L. Buhl	Battelle Ocean Sciences	T: 781-934-0571 F: 781-934-2124 E: buhl@battelle.org
Mr. Roy J. Covert	AIHA/Covert & Associates	T: 615-824-2543 F: 615-824-2543 E:
Mr. Stan Morton	U.S. Department of Energy	T: 208-526-2186 F: 208-526-5964 E: mortonjs@id.doe.gov
Ms. Marlene Patillo	Maryland Department of the Environment	T: 410-631-3510 F: 410-631-3733 E:
Ms. Athene M. Steinke	EA Laboratories	T: 410-771-4920 F: 410-771-4407 E: amt@eaest.com
Mr. William S. Toth	Worldwide Solutions for Tomorrow	T: 304-789-8684 F: E:
Mr. Owen S. Crankshaw (Contractor Support)	Research Triangle Institute	T: 919-541-7470 F: 919-541-7386 E: osc@rti.org
Ms. Lisa C. Greene (Contractor Support)	Research Triangle Institute	T: 919-541-7483 F: 919-541-7386 E: lcg@rti.org